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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,584	12/20/2001	Michael V. Chobotov	24641-1120	4975

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

17

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/029,584

Applicant(s)

CHOBOTOV ET AL

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-20,22-37 and 62-90 is/are pending in the application.
- 4a) Of the above claim(s) 7-10,26-29,36 and 79-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,12-20,22-25,30-35,37,62-67,69-72,74-78 and 83-90 is/are rejected.
- 7) ☒ Claim(s) 68 and 73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 15.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 12/15/03 has been entered as Paper No. 16. The changes to the specification have been approved by the examiner, and the objection to the drawings has been withdrawn. Claims 2, 11, 21 and 38-61 have been canceled and new claims 62-90 have been added. The claims pending are 1, 3-10, 12-20, 22-37 and 62-90. Claims 7-10, 26-29 and 36 remain withdrawn from consideration, and new claims 79-82 have also been withdrawn from further consideration for being drawn to a non-elected species. The claims currently being considered for further examination on the merits are 1, 3-6, 12-20, 22-25, 30-35, 37, 62-78 and 83-90.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the written specification or figures for the limitation of the inflatable channel being helically shaped, and it therefore constitutes new matter.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 30 is indefinite because it contradicts claim 20, on which it depends. Claim 20 requires that the looped portion is formed of a layer that is secured to itself, and then claim 30 requires that the loop portion is formed of a layer that is secured to another layer.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser et al. (USPN 6,149,681, as cited in previous office action).

Houser et al. discloses an implantable vascular graft with all the elements of claims 19 and 34. See Figures 8 and 9 and column 8, lines 33-51 for an endovascular graft (76) comprising a flexible material portion (80) and a transversely oriented member/connector member (90) secured to the flexible material portion with a means for joining that includes at least one flap means (92) of the flexible material folded back to form a loop portion that is secured to itself (at 94). The graft configuration shown in Figure 9 provides the loop with a configuration that is

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inherently capable of transferring tensile force on the transversely oriented member/connector member into a shear component of force on the flap and flexible material portion.

7. Claims 62 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Layne (USPN 6,558,414 as cited in applicant's IDS).

Layne discloses an endovascular graft with all the elements of claim 62. See Figure 4 and columns 3-4, lines 57-6 for a generally tubular flexible material portion (20) and a serpentine expandable member (30) circumferentially oriented about a circumference of the generally tubular flexible material portion (20). The expandable member (30) is secured to the generally tubular flexible material portion with a joint that includes at least one flap (50) of the flexible material folded back and secured to form a loop portion about the expandable member (30).

Claim 63, see Figure 4 for first and second set of apices directed in opposite directions. When the flaps are folded down, the apices of the first set will have a portion, providing as connector elements, that extends in a direction substantially parallel to the longitudinal axis of the generally tubular flexible material portion and beyond an edge of the generally tubular flexible material portion.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3-5, 13-18, 20, 22-24, 32, 33, 35, 69-72, 74-77 and 84-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of McDermott et al. (USPN 6,312,462 as cited in applicant's IDS).

Houser et al. discloses an implantable vascular graft with all the elements of claims 1, 20, 35, 69, 74 and 90, but is silent to the flexible material portion comprising a plurality of layers. See Figure 9 for at least one flap (92) of the flexible material being folded back and secured to itself to form a loop portion about the transversely oriented member/connector member (90). The method of forming a joint disclosed in column 8, lines 33-51 of fixing a flap (92) of the flexible material portion (80) about at least a portion of the connector member (90) provides a configuration that is inherently capable of transferring the tensile force on the connector member into a shear force on the fixed portion of the flap. McDermott et al. teaches an implantable vascular graft with a flexible material portion comprising two layers (34, 36). An inflatable channel that is helically shaped (claim 70; see Figure 7) or of circumferential rings (claim 71; see Figure 5) is formed between the two layers so that following insertion of the device into the vessel, a fluid can be injected between the layers into the channel to conform the graft to the vessel wall. See column 3, lines 8-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of McDermott et al. to modify the vascular graft of Houser et al. by having the flexible material portion comprise two layers with a channel formed therebetween in order to conform the graft to the vessel well upon injection of a fluid in the channel. This will help prevent blood from leaking around the graft. When the two layered flexible material portion is folded over, the loop portion will be formed of a layer, specifically the outer layer (36), that is secured to itself (claim 72).

Claims 3, 4, 22, 23, 75 and 76, see column 7, lines 19-20 and 50-58 for transversely oriented member/connector member comprises a material, nickel titanium, having a higher strength relative to the strength of the flexible material.

Claims 5, 24 and 77, see column 8, lines 47-49 for securing the flap by bonding with an adhesive to the flexible material of the graft or section thereof.

With respect to claims 12, 31 and 83, Houser et al. does not disclose the at least one flap being specifically about 1 to 25 square millimeters. In Figure 8 of Houser et al., it is clear that the length of the flap (92) corresponds to the length of the top of the transversely oriented member/connector member around which the loop is formed. Because the length of top of the transversely oriented member/connector member determines the circumference of the vascular graft formed, variation in the length will provide grafts of different diameters made for different sized vessels. A graft having a small diameter will therefore have a small flap area. Because the size of the graft will depend on the needs of the individual patient, it is obvious that the flap area required by claims 12, 31 and 83 will be met by the implantable vascular graft of Houser et al.

Claims 13, 14, 32, 33, 84 and 85, see Figure 8 and column 8, lines 39-51 for the joint comprising a plurality of flaps, one flap around each of the top and bottom of the rectangular transversely oriented member/connector member (90) folded back and secured to itself to form loop portions about the transversely oriented member/connector member.

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Claims 15-18 and 86-89, see abstract, column 7, lines 20-22 and column 8, lines 7-8 for transversely oriented member limitations.

10. Claims 6, 25, 37 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. and McDermott et al. as applied to claims 5, 24, 35 and 77 above, and further in view of Edwin et al. (USPN 6,245,099 as cited in previous office action).

Houser et al., as modified by McDermott et al., discloses an implantable vascular graft with all the elements of claims 5, 24, 35 and 77, but is silent to the adhesive being FEP or PFA, as required by claims 6, 25, 37 and 78 and of the flexible material portion comprising ePTFE, as also required by claim 37. Edwin et al. teaches a graft wherein FEP is introduced between layers of ePTFE in order to selectively bond the layers together. See column 8, lines 40-45. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Edwin et al. to make the flexible material portion of Houser et al. and McDermott et al. from the material well known in the vascular graft art, ePTFE, and to use FEP as the adhesive in Houser et al. to secure the flap to flexible material because it is well known in the art to effectively bond ePTFE to ePTFE. This will prevent the flap from separating from the flexible material during use.

11. Claims 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne in view of McDermott et al.

Layne discloses an endovascular graft with all the elements of claim 62, but is silent to the flexible material portion comprising a plurality of layers, wherein two adjacent layers are

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selectively attached to each other to form an inflatable channel therebetween, as required by claim 64. McDermott et al. teaches an implantable vascular graft with a flexible material portion comprising two layers (34, 36). An inflatable channel that is helically shaped (claim 65; see Figure 7) or of circumferential rings (claim 66; see Figure 5) is formed between the two layers so that following insertion of the device into the vessel, a fluid can be injected between the layers into the channel to conform the graft to the vessel wall. See column 3, lines 8-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of McDermott et al. to modify the vascular graft of Layne by having the flexible material portion comprise two layers with a channel formed therebetween in order to conform the graft to the vessel wall upon injection of a fluid in the channel. This will help prevent blood from leaking around the graft. When the two layered flexible material portion is folded over, the loop portion will be formed of a layer, specifically the outer layer (36), that is secured to itself (claim 67).

Allowable Subject Matter

12. Claims 68 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
13. Claim 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

14. Applicant's arguments with respect to claims 1, 3-6, 12-20, 22-25, 30-35, 37, 62-78 and 83-90 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

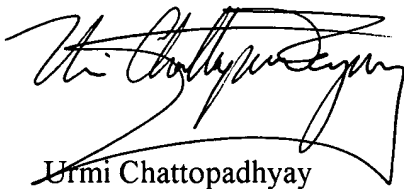
15. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/15/03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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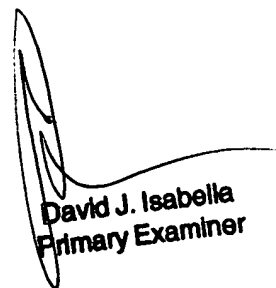
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner